Citation:

James J, Thomas P, Cavan D, Kerr D. Preventing childhood obesity by reducing consumption of carbonated drinks: cluster randomised controlled trial. *BMJ*. 2004 May 22;328(7450):1237. Epub 2004 Apr 23.

PubMed ID: 15107313

Study Design:

Randomized controlled trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To determine if a school-based educational program for reducing consumption of carbonated beverages could prevent excessive weight gain in children.

Inclusion Criteria:

Children aged 7 to 11 years in six junior schools, as part of the Christchurch Obesity Prevention Project in Schools (CHOPPS).

Exclusion Criteria:

Children without parental consent, who were absent, who refused to participate, moved school, whose age was <7 or >11 years. Classes of students of mixed ages.

Description of Study Protocol:

Recruitment

Part of the Christchurch Obesity Prevention Project in Schools (CHOPPS).

Design

Anthropometric measurements taken (height, weight, waist circumference), three-day drink diaries collected.

One investigator delivered the program to all classes. Classes lasted for one hour session each term (4 terms total) over the course of one school year (August 2001 to October 2002). The main lesson objective to discourage the consumption of carbonated beverages (sweetened and unsweetened)

with positive affirmation of a balanced healthy diet.

Classes taught:

1. Focused on good health and promotion of drinking water, children tasted fruit to learn about the sweetness of natural products, and class was given a tooth immersed in a sweetened carbonated cola to assess its effect on dentition,
2. and 3. Music competition where children were given lyrics and were challenged to produce a song or a rap with a healthy message

4. Presentations of art and a classroom quiz based on a popular television game show.

Intervention and control clusters consisted of 6 junior schools (children age 7 to 11 years), equivalent to 29 clusters (15 randomized to intervention, 14 randomized to control; each class was considered a cluster). Average number of children per cluster: 22 (11 boys/11 girls).

Statistical Analysis

T tests (significance between intervention and control clusters), paired t test (significance of changes within clusters) Searle's method to calculate intracluster correlation coefficients.

Data Collection Summary:

Timing of Measurements

Body mass index was measured at baseline, 6 months ad 12 months.

Dependent Variables

Body mass index

Independent Variables

Beverage intake

Control Variables

Number of students per cluster

Description of Actual Data Sample:

Initial N: 914

Attrition (final N): 644

Age: 7 to 11 years

Location: Southwest England

Summary of Results:

Average age at baseline was 8.7±0.9 (range 7.0 to 10.9).

Carbonated Drinks

Consumption of carbonated drinks over three days decreased by 0.6 glasses (average glass size 250 ml) in the intervention group but increased by 0.2 glasses in the control group (mean difference 0.7, 95% CI 0.1 to 1.3).

Overweight

At 12 months, the mean percentage of overweight and obese children increased in the control clusters by 7.5% compared with a decrease in the intervention group of 0.2% (mean difference 7.7%, 95% CI 2.2 to 13.1%).

Overall 55% of the children returned the first drink diary (338 of 615) and 56% returned the second (321 of 574); 36% returned both (235). Overall, 19% of the children who did or did not return diaries at baseline were overweight.

At the end of 12 months, both the intervention and control group showed a significant increase in consumption of water.

Author Conclusion:

A targeted, school-based education program produced a modest reduction in the number of carbonated drinks consumed, which was associated with a reduction in the number of overweight and obese children.

Reviewer Comments:

Strengths:

- *Contamination by transfer of knowledge would have been minimized by cluster randomization design.*

Limitations:

- *Contamination – randomization was according to classes, not schools – transfer of knowledge may have taken place outside the classroom.*
- *Validity of self-reported dietary data can be questioned (under-reporting of energy intake, particularly among the overweight or obese)*

Other Comments:

- *Final sample study numbers do not match (are not clear, particularly after 6 and 12 month follow-up and differences between drink diary participant numbers and anthropometric measurement participant numbers).*
- *No controlling for total energy intake.*
- *Appropriate for American populations?*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	N/A
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	N/A

Validity Questions

1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	Yes

3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	???
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	???
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	???
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes

6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	N/A
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	No
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	No
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes

9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes